Bioprocess Validation and Quality Control (BENG0041)

Description
The course addresses the challenge of the safe delivery to patients of biopharmaceuticals and in particular injectables. The aim of the course is to familiarise students with current validation methodology using leading edge developments with expert speakers in a workshop format. Particular focus is given to development of concepts of Critical Quality Attributes (CQAs), Critical Process Parameters (CPPs) and Quality by Design (QbD).

Upon completion of the course, a student should be able to:

- Assess new process concepts and judge key issues to be addressed before regulatory acceptability for manufacture will be achievable
- Collect the information required and validate a process and the resources requested to manage the implementation of a stage leading to full validated status
- Communicate with validation experts
- Understand what is required by the regulatory authorities for compliance including future direction of the regulations
- Understand the implications of validation for process development
- Familiarise with current validation practice across the bioprocess industry
- Understand the role of validation and quality control in ensuring public protection
- Develop communication skills including prepare a validation plan

Key information

<table>
<thead>
<tr>
<th>Year</th>
<th>2018/19</th>
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</thead>
<tbody>
<tr>
<td>Credit value</td>
<td>15 (150 study hours)</td>
</tr>
<tr>
<td>Delivery</td>
<td>PGT L7, Campus-based</td>
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<tr>
<td>Reading List</td>
<td><a href="https://www.ucl.ac.uk">View on UCL website</a></td>
</tr>
<tr>
<td>Tutor</td>
<td>Miss Chika Nweke</td>
</tr>
<tr>
<td>Term</td>
<td>Term 2</td>
</tr>
<tr>
<td>Timetable</td>
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</tbody>
</table>

Assessment

- Coursework: 70%
- Coursework: 30%

Find out more

For more information about the department, programmes, relevant open days and to browse other modules, visit [ucl.ac.uk](https://www.ucl.ac.uk)
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Disclaimer: All information correct as of December 2018. Please note that aspects of the module may be subject to change. UCL will make best efforts to inform applicants of major changes.